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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,877	01/22/2002	Marc F. DeCristofaro	21402-251 (Cura-551)	9411

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,877	DECRISTOFARO ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, and 32, drawn to an isolated polypeptide, and a composition and kit comprising the polypeptide, classified in class 530, subclass 350.

II. Claims 5-14, 30, and 33, drawn to an isolated nucleic acid, and a vector, cell, composition and kit comprising the nucleic acid, classified in class 536, subclass 23.1.

III. Claim15-17, 31, and 34, drawn to an antibody, and a composition and kit comprising the antibody, classified in class 530, subclass 287.1.

IV. Claim 18, drawn to a method to detect and measure a polypeptide, classified in class 435, subclass 7.1.

V. Claim 19, drawn to drawn to a method to detect and measure a nucleic acid, classified in class 435, subclass 6.

VI. Claim 20, drawn to a method to identify a compound which binds a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to method to identify a modulator of peptide activity, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method to modulate the activity of a peptide, classified in class 435, subclass 183.

IX. Claims 23-24 and 40, drawn to a method of treatment using a peptide, classified in class 514, subclass 2.

X. Claims 25-26, drawn to a method of treatment using a nucleic acid, classified in class 514, subclass 23.

XI. Claims 27-28 and 41, drawn to a method of treatment using an antibody, classified in class 424, subclass 130.1.

XII. Claim 35, drawn to use of a therapeutic agent, classified in class 424, subclass 130.1.

XIII. Claims 36-37, drawn to a screening assay, classified in class 424, subclass 9.2.

XIV. Claim 38, drawn to a method to detect or determine a predisposition to a disease using a peptide, classified in class 435, subclass 7.1.

XV. Claim 39, drawn to a method to detect or determine a predisposition to a disease using a nucleic acid, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Groups I, IV, VI-IX, and XII-XIV are each separate and distinct from each of Groups II, V, X and XV because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups II, V, X and XV, the critical feature is a polypeptide whereas for Groups I, IV, VI-IX, and XII-XIV the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Each of Inventions II, V, X and XV is separate and distinct from each of Groups III and XI as the claims of Inventions II, V, X and XV are drawn to polynucleotides, while the claims of Groups III and XI are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions III and XI would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Each of Inventions I, IV, VI-IX, and XII-XIV is separate and distinct from Inventions III and XI as the polypeptides of Inventions I, IV, VI-IX, and XII-XIV are structurally and biochemically different than the antibody of Invention III. While the antibody of Groups III and XI may bind to the polypeptide of Group I, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner. Inventions I, IV, VI-IX, and XII-XIV are therefore separate and distinct from each of Inventions III and XI.

Invention I is related to Inventions IV, VI-IX, and XII-XIV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in any of the different methods of Groups IV, VI-IX, and XII-XIV.

Invention II is related to Inventions V, X, XII, and XV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used in any of the different methods of Groups V, X, XII, and XV.

Invention III is related to Inventions X and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group III can be used in any of the different methods of Groups X and XII.

Groups IV, VI-IX, and XII-XIV are separate and distinct. Although the Groups are related in that each recites use of a polypeptide, the method of each Group is directed to a different result and recites different method steps requiring a search different from that of any other Group. In addition, the method of any one Group may be performed without knowledge of or reference to the steps or results of the method of any other Group.

Groups V, X, XII, and XV are separate and distinct. Although the Groups are related in that each recites use of a polynucleotide, the method of each Group is directed to a different result and recites different method steps requiring a search different from that of any other Group. In addition, the method of any one Group may be performed without knowledge of or reference to the steps or results of the method of any other Group.

Groups X and XII are separate and distinct. Although the Groups are related in that each recites use of an antibody, the method of each Group is directed to a different result and recites different method steps requiring a search different from that of any other Group. In addition, the method of any either Group may be performed without knowledge of or reference to the steps or results of the method of the other Group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In addition, these inventions are distinct for the reasons given above and the search required for Groups II-XV is not required for Group I, the search for Groups III-XV is not required for Group II, the search for Groups II and IV-XV is not required for Group III, and the search for any one method is not required for any other method, therefore restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363 until January 12, 2004. After that date, the telephone number will be (571)272-0720. The examiner can normally be reached on Monday to Wednesday, 7:30 am to 4 pm EST, Thursday, 7:30 am to 6 pm EST, and Friday, 7 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran

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